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REMARKS

Pages 10, 16, 26, 28 and 35 of the specification have been amended. The Abstract has also been amended. Claims 127, 139 and 165 have been amended and claims 136-138, 163-164 and 170 canceled. Claims 127-135, 139-162 and 165-169 are pending. Reconsideration of the application, as amended, is requested.

Pages 10, 16, 26, 28 and 35 of the specification have been amended to update patent application and PCT application data. The Abstract has been amended to be less than 150 words. Claim 127 has been amended to clarify that the second conductive material is one the first or the second surface and to incorporate the limitations of claims 136, 137 and 138. Claims 139 and 165 have been amended to change their dependence from a now-canceled claim to claim 127.

Pending Claims

The pending claims are directed to a specific embodiment of an electrochemical sensor having a flexible, planar substrate with one or more working electrodes on a first side of the substrate and a counter or reference electrode on the first side or a second side of the substrate. The sensor has a specific shape, with a wide portion and a narrow portion, the narrow portion having a length of 2 cm or less and a width of 2 mm or less. An enzyme is proximate the working electrode, and an analyte mass transport limiting layer is present over at least a portion of the working electrode. Pending claims 127-135 and 139-162 and 165-166 are directed to the sensor, and claims 167-169 are directed to methods of determining a level of an analyte in a fluid using the sensor.

§102 Rejections

Claims 127-140, 148-152 and 160-170 were rejected under 35 U.S.C. § 102(b) as being anticipated by Kurnik et al, U.S. Patent No. 5,827,183. Applicants disagree.

Claim 127, the independent sensor claim, recites, among other features:

a flexible, planar substrate;

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a first conductive material non-leachably disposed on a first surface of the planar substrate to form one or more working electrodes;

a second conductive material non-leachably disposed on the first surface or a second surface of the planar substrate to form a counter electrode, a reference electrode, or a counter-reference electrode;

the sensor having a wide portion and a narrow portion, the narrow portion having a length of 2 cm or less and a width of 2 mm or less, and the narrow portion configured and arranged for subcutaneous implantation into the body of an animal.

There is no disclosure in the Kurnik et al. reference of a sensor having a planar substrate with working electrodes configured as recited by pending claim 127, the sensor having a wide portion and a narrow portion, with a specific dimension for the narrow portion.

At least for this reason, claim 127 is not anticipated by the Kurnik et al. reference, and is allowable. Claims 128-135, 139-162 and 165-169 are allowable over Kurnik et al., at least because they incorporate all the elements of claim 127 therein. Claims 128-135, 139-162 and 165-169 also include additional elements over claim 127.

The Examiner states that it is inherent that the structure of Kurnik et al. includes a substrate to support the electrodes and mask. Applicants do not agree or disagree with this, but do assert that the Kurnik et al. reference does not disclose the various features of the substrate as recited by the independent claims (claim 127) and the dependent claims: that is, the substrate comprising a wide portion and a narrow portion, the narrow portion having a length of 2 cm or less and a thickness of 2 mm or less, the narrow portion configured for subcutaneous implantation into the animal (claim 127), a thickness in the range of 50-500µm, or 100-300µm (claims 134-135), the narrow portion having a width in the range of 1 mm or less, 0.5 mm or less (claims 139-140), a recessed channel formed in a surface of the substrate, and a conductive material disposed in the recessed channel and forming the working electrode (claim 148) having a width of 250 µm or less (claim 149), a second recessed channel and a second conductive material disposed in the

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recessed channel, the second conductive material forming a counter electrode (claim 150), a third recessed channel and a third conductive material disposed in the channel, the third conductive material forming a reference electrode (claim 151), and a biocompatible coating disposed over at least a portion of the working electrode (claim 152).

The Examiner's statement that Kurnik et al. discloses an ionically conductive material for the electrodes does not affect the pending claims. There is no disclosure in the Kurnik et al. reference that would anticipate claims 128-131, 165 and 166. There is no disclosure in Kurnik et al. that the conductive material could be carbon (claims 128, 129), Ag/AgCl (claim 130), or that the first and second conductive materials are the same (claim 131). There is also no disclosure of having one or more contact pads comprising conductive polymer (claim 165) and no disclosure of having one or more contact pads consisting essentially of carbon (claim 166).

As for claim 133, Kurnik et al. does not disclose two or more working electrodes, nor does Kurnik et al. disclose one or more contact pads in contact with the counter electrode, reference electrode or counter-reference electrode (claim 127).

At least for these reasons, the claims are not anticipated by Kurnik et al., and are allowable. Withdrawal of this rejection is requested.

§103 Rejections

Claims 141-147 were rejected under 35 U.S.C. § 103(b) as obvious over Kurnik et al, U.S. Patent No. 5,827,183, in view of Hill, U.S. Patent No. 5,509,410. Applicants disagree.

Kurnik et al., and its applicability to the pending claims, was discussed above. Claim 127 is allowable over Kurnik et al., as discussed above, and Hill does not remedy the deficiencies of Kurnik et al. By adding the electron transfer mediator to the sensor of Kurnik et al., one does not arrive at the pending claims.

At least for these reasons, the claims are not obvious, and withdrawal of this rejection is requested.

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Claims 159 and 162 were rejected under 35 U.S.C. § 103(b) as obvious over Kurnik et al, U.S. Patent No. 5,827,183. Applicants disagree.

Kurnik et al., and its applicability to the pending claims, was discussed above. The knowledge of using an anticlotting agent does not make obvious the claims in view of Kurnik et al. Claim 127 is allowable over Kurnik et al., and so is claim 159.

Regarding claim 162, there is no disclosure or teaching in Kurnik et al. to have a porous mask. Rather, the Kurnik et al. reference merely discloses a central hole in the mask that corresponds to the working electrode. Pending claim 162 recites a porous layer, having pores of 3 to 20,000 nm. Kurnik et al. discloses a hole of 0.8 cm in the mask. It would not be obvious to have pores of 3 to 20,000 nm when a single hole of 0.8 cm is disclosed. At least for these reasons, claim 162 is allowable.

At least for these reasons, the claims are not obvious, and withdrawal of this rejection is requested.

Allowable Subject Matter

Claims 153-158, 160 and 161 were objected to as dependent on a rejected base claim, but would be allowable if rewritten in independent form. Applicants contend that all claims are allowable.

Information Disclosure Statement

Applicants thank the Examiner for returning initial copies of the 1449 forms. However, Applicants note that not all the references listed on Sheet 9 of 20, dated October 10, 2000, were initial by the Examiner. Applicants request that the Examiner review the references listed thereon and return the initialed sheet. For the Examiner's convenience, a replacement Sheet 9 of 20 is attached herewith, having the date changed to May 21, 2002, the date of filing of this paper.

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SUMMARY

Applicants submit that the claims are in proper form for allowance and respectfully request reconsideration and allowance thereof. A Notice of Allowance is requested.

Attached is a marked-up version of the amendments made to the application by the current amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE".

The Examiner is invited to contact the undersigned representative if it will facilitate prosecution of this application.

Respectfully Submitted,

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